

NB: this is a summary translation of the
press release original drafted in Japanese
for the disclosure required in compliance
with the TSE regulations.

Non-consolidated Financial Results for the Three Months Ended March 31, 2023 [Japanese GAAP]



May 12, 2023

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Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
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Scheduled date of filing quarterly securities report: May 12, 2023
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: No

(Amounts of less than one million yen are rounded down.)

1. Financial Results for the Three Months Ended March 31, 2023 (January 1, 2023 to March 31, 2023)

(1) Operating Results (% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
March 31, 2023	35	(81.9)	(325)	-	(323)	-	(323)	-
March 31, 2022	193	-	(384)	-	(349)	-	(328)	-

	Basic earnings per share	Diluted earnings per share
Three months ended	Yen	Yen
March 31, 2023	(18.69)	-
March 31, 2022	(18.98)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of March 31, 2023	2,280	1,835	80.1
As of December 31, 2022	2,650	2,159	81.2

(Reference) Equity: As of March 31, 2023: ¥1,827 million

As of December 31, 2022: ¥2,151 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended December 31, 2022	Yen -	Yen 0.00	Yen -	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2023	-				
Fiscal year ending December 31, 2023 (Forecast)		0.00	-	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2023 (January 1, 2023 to December 31, 2023)

Financial results forecast is not disclosed due to the difficulty of making reasonable estimates. For details, please see “1. Qualitative Information on Quarterly Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information on page 2 of the supplementary material.

* Notes:

- (1) Accounting policies adopted specially for the preparation of quarterly financial statements: No
- (2) Changes in accounting policies, changes in accounting estimates and retrospective restatement
 - 1) Changes in accounting policies due to the revision of accounting standards: No
 - 2) Changes in accounting policies other than 1) above: No
 - 3) Changes in accounting estimates: No
 - 4) Retrospective restatement: No
- (3) Total number of issued shares (common shares)
 - 1) Total number of issued shares at the end of the period (including treasury shares):
March 31, 2023: 17,405,200 shares
December 31, 2022: 17,405,200 shares
 - 2) Total number of treasury shares at the end of the period:
March 31, 2023: 86,238 shares
December 31, 2022: 82,238 shares
 - 3) Average number of shares during the period:
Three months ended March 31, 2023: 17,319,139 shares
Three months ended March 31, 2022: 17,332,511 shares

* These quarterly financial results are outside the scope of quarterly review by certified public accountants or an audit corporation.

* Explanation of the proper use of financial results forecast and other notes

(Note regarding forward-looking statements, etc.)

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of the release of these materials and certain assumptions deemed reasonable, and do not represent a commitment from the Company that they will be achieved. In addition, actual financial results, etc. may differ significantly due to a wide range of factors. For the assumptions used in forecasting financial results and notes regarding the use of financial forecasts, etc., please see “1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information” on page 2 of the supplementary material.

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1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of Business Results

During the three months ended March 31, 2023, the Japanese economy was constrained in its recovery from the COVID-19 pandemic, having been unable to keep pace with historic price hikes despite the March announcement of the first significant wage increase in 30 years, and the Bank of Japan's Tankan survey for March, released in April, showed a fifth consecutive quarter of deterioration in the manufacturing sector. In addition, the outlook for the global economy is becoming increasingly uncertain due to the prolonged crisis in Ukraine and a substantial economic deceleration in countries around the world due to monetary tightening by the U.S. Federal Reserve Board (FRB) and other major central banks.

Under these circumstances, the Company has been pursuing a vision of "Dedicating power to future cancer treatments, and leaving our footprint in the history of cancer treatment through those achievements," thus striving to increase managerial efficiency and actively expand research, development, and licensing activities.

In particular, the Company is promoting research, development, and licensing activities with the aim of "virus drug discovery" within the business fields of "virotherapy for cancer" and "drugs for the treatment of serious viral infectious diseases," with a focus on Telomelysin (OBP-301), a virotherapy for cancer, and OBP-2011 for the treatment of COVID-19. In addition, concerning OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor, Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting multiple clinical trials in Europe and the U.S. entirely at its own expense based on a license agreement.

For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

For the three months ended March 31, 2023, net sales were ¥35,000 thousand (net sales of ¥193,125 thousand in the same period of the previous fiscal year), and operating loss was ¥325,578 thousand (operating loss of ¥384,747 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥149 thousand and foreign exchange gains of ¥3,192 thousand as non-operating income, and interest expenses of ¥855 thousand as non-operating expenses. As a result, ordinary loss was ¥323,092 thousand (ordinary loss of ¥349,628 thousand in the same period of the previous fiscal year). Moreover, gain on sale of non-current assets of ¥136 thousand was recorded as extraordinary profit. As a result, net loss was ¥323,691 thousand (net loss of ¥328,960 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the first quarter of the fiscal year under review were ¥2,280,737 thousand (14.0% decrease compared with the end of the previous fiscal year), primarily due to a decrease in cash and deposits. Liabilities were ¥445,159 thousand (9.5% decrease compared with the end of the previous fiscal year), mainly on account of a decrease in accounts payable - other. Net assets were ¥1,835,577 thousand (15.0% decrease compared with the end of the previous fiscal year), due to net loss incurred, as well as other factors.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on contractual lump-sum payments from the conclusion of new contracts and milestone revenue payments generated from licensees achieving events. There is also a risk that disclosing our full-year earnings forecast for the fiscal year ending December 31, 2023 could affect our negotiations on economic terms for the Telomelysin domestic distribution partnership agreement planned for 2023, as well as our negotiations on terms for the Telomelysin collaborative research with a major pharmaceutical company in the United States that markets an immune checkpoint inhibitor.

For these reasons, we believe that it is difficult to calculate an appropriate and reasonable figure for the earnings forecast at this time due to the many undetermined factors that will affect our business performance, and therefore, we refrain from disclosing the forecast. In addition, since the Company manages its performance

annually, the Company omits the description of its earnings forecasts for the second quarter (cumulative).

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2022	As of March 31, 2023
Assets		
Current assets		
Cash and deposits	1,711,280	1,408,789
Accounts receivable – trade	-	38,500
Finished goods	8,434	6,124
Work in process	12,666	-
Supplies	3,149	2,900
Advance payments – other	506,316	550,627
Prepaid expenses	47,970	34,869
Short-term loans receivable from subsidiaries and associates	39,813	13,354
Accounts receivable – other	174,310	41,112
Income taxes refund receivable	28,299	28,299
Consumption taxes receivable	75,982	85,884
Advances paid	29	-
Other	501	9
Total current assets	2,608,754	2,210,471
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	-	-
Tools, furniture and fixtures	65,939	65,939
Accumulated depreciation	(65,939)	(65,939)
Tools, furniture and fixtures, net	-	-
Total property, plant and equipment	-	-
Investments and other assets		
Shares of subsidiaries and associates	20,936	20,936
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	-	26,708
Lease and guarantee deposits	21,149	21,149
Long-term prepaid expenses	-	1,353
Other	19	19
Total investments and other assets	42,204	70,265
Total non-current assets	42,204	70,265
Total assets	2,650,959	2,280,737

(Thousand yen)

	As of December 31, 2022	As of March 31, 2023
Liabilities		
Current liabilities		
Short-term loans payable	227,776	211,116
Lease obligations	3,581	3,601
Accounts payable – other	60,858	51,612
Accrued expenses	17,099	12,999
Income taxes payable	2,931	5,443
Deposits received	9,392	8,395
Total current liabilities	321,639	293,168
Non-current liabilities		
Long-term loans payable	155,544	138,876
Lease obligations	6,758	5,850
Provision for retirement benefits	7,748	7,265
Total non-current liabilities	170,051	151,991
Total liabilities	491,690	445,159
Net assets		
Shareholders' equity		
Capital stock	3,000,000	3,000,000
Capital surplus		
Legal capital surplus	586,425	586,425
Total capital surpluses	586,425	586,425
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(1,434,694)	(1,758,385)
Total retained earnings	(1,434,694)	(1,758,385)
Treasury shares	(142)	(142)
Total shareholders' equity	2,151,589	1,827,897
Share acquisition rights	7,680	7,680
Total net assets	2,159,269	1,835,577
Total liabilities and net assets	2,650,959	2,280,737

(2) Quarterly Statements of Income
Three Months Ended March 31

(Thousand yen)

	For the three months ended March 31, 2022	For the three months ended March 31, 2023
Net sales	193,125	35,000
Cost of sales	65,641	32,433
Gross profit	127,483	2,566
Selling, general and administrative expenses	512,231	328,145
Operating loss	(384,747)	(325,578)
Non-operating income		
Interest income	153	149
Foreign exchange gains	39,380	3,192
Total non-operating income	39,533	3,341
Non-operating expenses		
Interest expenses	864	855
Amortization of restricted stock remuneration	3,520	-
Share issuance costs	30	-
Total non-operating expenses	4,415	855
Ordinary loss	(349,628)	(323,092)
Extraordinary income		
Gain on sale of bonds	21,406	-
Gain on sale of non-current assets	-	136
Total extraordinary income	21,406	136
Loss before income taxes	(328,222)	(322,955)
Income taxes - current	738	736
Total income taxes	738	736
Loss	(328,960)	(323,691)

(3) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

There is no relevant information.

(Segment information, etc.)

[Segment information]

I. For three months ended March 31, 2022

The information is omitted, as the Company consists of a single segment of the drug discovery business.

II. For three months ended March 31, 2023

The information is omitted, as the Company consists of a single segment of the drug discovery business.

(Revenue recognition)

Disaggregation of revenue from contracts with customers

(Thousand yen)

	For the three months ended March 31, 2022	For the three months ended March 31, 2023
Goods / Services transferred at a point in time	36,287	35,000
Goods / Services transferred over time	156,838	---
Revenue from contracts with customers	193,125	35,000
Revenue from other sources	---	---
Net sales to outside customers	193,125	35,000

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the three months ended March 31, 2023 totaled ¥179,157 thousand for the drug discovery business. The status of research and development activities during the fiscal year under review is as follows.

(1) Research and development structure

As of March 31, 2023, 18 persons belonged to research and development department, equivalent to 48.7% of the total number of employees.

(2) Research and development and business activities

The Company promoted research and development, and business activities centered on the following projects.

1) Activities related to Telomelysin (OBP-301) (International Nonproprietary Name: suratadenoturev) virotherapy for cancer

The Company is conducting a “Phase II clinical trial in combination with radiation therapy for esophageal cancer” for Telomelysin, for which the Ministry of Health, Labour and Welfare has granted “SAKIGAKE designation” for regenerative medicine products in Japan. We have already completed enrollment of patients and are following up on the prognosis of all cases, with plans to file for approval in Japan in 2024. We have also made progress in viral production development on a commercial manufacturing scale and advance discussions are underway with the PMDA to apply for approval. On the other hand, we have begun preparing to establish our own manufacturing and sales system, and we have started due diligence and negotiations on terms and conditions for an alliance with companies that are candidates to be our marketing partners. In addition, discussions are underway with a major foreign pharmaceutical company that markets immune checkpoint inhibitors for the joint development of Telomelysin in the U.S.

Currently, Telomelysin is undergoing the following three clinical trials in Japan and overseas, including the clinical trial for which enrollment has been completed:

- i) Phase II clinical trial in combination with radiation therapy for esophageal cancer;
- ii) Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer; and
- iii) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

Regarding the above i) “Phase II clinical trial in combination with radiation therapy for esophageal cancer,” trials are ongoing based on the “SAKIGAKE designation” of April 2019 at 17 clinical trial sites around Japan, and we confirmed that the target number of patients for this clinical trial was reached in December 2022. We are currently conducting a follow-up study to determine the prognosis of cases, and the results for the primary endpoint of this trial, the local response rate in esophageal cancer, are expected to be available in the second half of 2023. To ensure the safety of study participants, safety information is monitored as the study progresses, although to date, no safety issues have emerged that would require the suspension of this clinical trial.

In addition, the Company is currently moving forward on GMP manufacturing development for commercial production at Belgium’s Henogen SA with a view to submitting an application for approval in 2024. The system that we are now putting in place will enable the smooth transport of Telomelysin to medical institutions in Japan. After having been formulated at Henogen and imported to Japan while held at a temperature range of minus 80 degrees, it will be repackaged for domestic sales and decisions made to determine shipping. Furthermore, to ensure efficient sales in Japan, we are undertaking negotiations to partner with pharmaceutical companies.

Regarding the above ii) “Phase II investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for gastric cancer/gastroesophageal junction cancer,” administration began in May 2019 led by Cornell University in the U.S. with the goal of evaluating the efficacy and safety of Telomelysin and pembrolizumab, and was performed for the most advanced patients who have been treated over two times in the past. Long-term survival has been confirmed in 3 of the 16 patients enrolled so far. This result confirmed that it satisfied the standard set for efficacy in the trial, and as we were unable to enroll up to 18 patients, we decided to terminate enrollment in this clinical trial at the end of 2022, ahead of schedule. In order to conduct a new investigator-initiated clinical trial for second-line treatment of gastric cancer that has not responded to immune checkpoint inhibitor plus chemotherapy treatment, we are now in discussions with a pharmaceutical company, a

marketer of immune checkpoint inhibitors, with the goal of co-development. We plan to conclude the same agreement in 2023.

Regarding the above iii) “Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer,” NRG Oncology, a leading cancer research group in the U.S., has been leading the trial, and administration began in December 2021 with the primary purpose of investigating the safety and efficacy of using Telomelysin in combination with chemoradiotherapy. This clinical trial is currently being conducted in six facilities within the U.S., and the enrollment of six patients has been completed. Thus far, there have been no reports of problematic side-effects. Telomelysin has been designated as an orphan drug for esophageal cancer in the U.S., and this clinical trial is being conducted on that basis. Therefore, in addition to being able to consult with the FDA for advice in conducting clinical trials, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. Furthermore, first-mover rights protection will be granted for seven years after the approval of Telomelysin in the U.S. and market exclusivity will be granted during that period.

In addition to the above, “Phase I investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors,” led primarily by the National Cancer Center Hospital East, has already been concluded. The trial’s objective was accomplished after having confirmed treatment with a combination of Telomelysin and pembrolizumab was safe in a total of 22 esophageal cancer patients who had previously been treated multiple times. The results of the trial were announced at the American Association for Cancer Research (AACR) Annual Meeting in the U.S. in April 2023.

2) Activities related to OBP-601 (Censavudine), a nucleoside reverse transcriptase inhibitor

The Company licensed in OBP-601 from Yale University in 2006. From 2010 to 2014, it was licensed to Bristol-Myers Squibb Co. (hereinafter “BMS”), which conducted Phase II clinical trials as a treatment drug for HIV infection. The results demonstrated the non-inferiority of OBP-601 to existing drugs. During the same period, BMS also obtained numerous clinical safety data for long-term OBP-601 toxicity studies and oncogenicity studies, but given BMS’s change of strategy, namely withdrawing from the HIV field, the license agreement was terminated.

Subsequently, results of a study by Brown University of the U.S. confirmed that OBP-601 has higher brain translocability than other nucleic acid-based reverse transcriptase inhibitors (NRTIs) and that OBP-601 strongly suppressed the aberrant expression of LINE-1, a retrotransposon that is thought to cause intractable neurological diseases. In June 2020, we concluded a new licensing agreement with Transposon, which focused on this phenomenon, worth more than \$300 million worldwide. In November of the same year, Transposon achieved its first milestone.

Transposon is currently conducting two double-blind Phase IIa clinical trials that make use of placebos at numerous facilities, both in Europe and the U.S. One covers progressive supranuclear palsy (PSP), while the other is on amyotrophic lateral sclerosis (ALS), with the abnormal expression of the enzyme C9 ORF, and frontotemporal degeneration (FTD). Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021, and enrollment of the target number of patients was concluded in August 2022. In addition, administration under the clinical trial for ALS and FTD began in January 2022, and target enrollment was concluded in March 2023. Thus far, there have been no reports of safety problems that necessitate the termination of the trials.

Transposon plans to report the results of the interim analysis of the Phase IIa clinical trial for PSP to the Company in 2023 and the interim analysis of the Phase IIa clinical trial for C9-ALS and FTD in 2024. These clinical trials on OBP-601 are proceeding entirely at Transposon’s expense.

Furthermore, Transposon is currently preparing to initiate a new Phase IIa clinical trial for Aicardi-Goutières Syndrome (AGS), a genetic disorder that causes microcephaly and severe mental retardation, and has received regulatory approval in Italy, France and the UK.

Transposon is a company that was established with the purpose of developing OBP-601. The Company therefore believes that the risk of Transposon suspending the development of OBP-601 due to a change in strategy is low.

3) Activities related to OBP-2011 for the treatment of COVID-19

Based on experimental outcomes, the Company assumes that OBP-2011 inhibits nucleocapsids, although the specific mechanism has not been clarified yet at this stage. It is speculated that OBP-2011 has a new mechanism that differs from the main mechanisms of polymerase and protease inhibition already approved for the treatment of coronaviruses, and data indicated that its effectiveness is not influenced by such factors as virus mutation. However, it has become necessary to revise the development policy as the hurdle has been raised for obtaining approval for our proposed COVID-19 treatment, at the same time as changes have emerged in the external environment, such as the reduced urgency due to the launch of multiple therapeutic drugs for COVID-19 to the market, and the concentration of management resources on Telomelysin, for which we aim to apply for approval in 2024. Going forward, the Company will proceed with clarifying the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and the National Institute of Infectious Diseases and will consider new indications for RNA viruses other than coronaviruses, maintaining a framework that can respond to new pandemics.

4) Activities related to next generation Telomelysin (OBP-702)

OBP-702 is a second-generation virotherapeutic drug with two anti-tumor effects, combining the “oncogene therapy” that carries the powerful cancer suppressor gene p53 in the vector with the “oncolytic functions” of Telomelysin. A research group led by Professor Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery, Transplant, and Surgical Oncology of Okayama University is conducting non-clinical trials on OBP-702, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED). In particular, an experiment on gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702, used in combination with PD-L1 antibodies, exhibited stronger anti-tumor effects alone.

It has also been shown to have a lethal effect on cancer associated fibroblasts (CAF), which are problematic in cancer therapy. It is expected that OBP-702 will be developed as a new treatment method for pancreatic cancer and other refractory cancers thought to have numerous fibroblasts. Development of OBP-702 will continue within the scope of the grant in order to concentrating management resources on Telomelysin, which we aim to submit for approval in 2024.

5) Activities related to TelomeScan (OBP-401), a cancer detection drug

Regarding TelomeScan, the Company set up a “Collaborative Research Program on Minimally Invasive Cancer Detection Method Using TelomeScan,” in June 2021, with Juntendo University, aimed at establishing a platform for automated detection of live Circulating Tumor Cells (CTC) within the blood of cancer patients. However, development progress has been delayed due to the time required to acquire images compared to initial plans, given the large number of images that need to be acquired for AI image learning.

6) Activities related to OBP-801, HDAC inhibitor

Regarding OBP-801, a histone deacetylase (HDAC) inhibitor licensed from Astellas Pharma Inc. in 2009, dose limiting toxicity (DLT) was observed in Phase I clinical trials targeting solid body cancers in the U.S., making it impossible to escalate the dosage to the presumed effective dose. Therefore, development in the field of cancer has been suspended.

On the other hand, research for application to glaucoma surgery has been carried out at the Department of Ophthalmology of Kyoto Prefectural University of Medicine in the ophthalmic field, which is a new area of indication for OBP-801, revealing that the drug suppresses fibrosis after filtering bleb formation from glaucoma surgery. The research results were presented at a meeting of the Japanese Ophthalmological Society in April 2023. Going forward, there is hope for development in the form of eye drops.

The development status of pipeline products is as follows.

Product	Indication	Combination therapy	Development region	Development stage
Telomelysin (OBP-301) (Suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II (Enrollment complete)
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (Enrollment complete)
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	U.S.	Phase II (Enrollment complete)
	Hepatocellular cancer (HCC)	Anti-PD-L1 antibody atezolizumab Molecular targeting drug	Japan	Phase I (complete)
		Monotherapy	South Korea and Taiwan	Phase I (complete)
OBP-601 (Censavudine)	Progressive supranuclear palsy (PSP)	Monotherapy	U.S.	Phase IIa (Enrollment complete)
	Amyotrophic lateral sclerosis (C9-ALS) / frontotemporal degeneration (FTD)	Monotherapy	U.S. and Europe	Phase IIa (Enrollment complete)
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Italy, France, and U.K.	Phase IIa
OBP-2011	Novel coronavirus infection (COVID-19)	TBD	Japan	Pre-clinical
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	-	Japan	Clinical research
OBP-801	Suppression of filtering bleb fibrosis after glaucoma surgery	Monotherapy	Japan	Pre-clinical